REMARKS

The present Office Action addresses and rejects claims 1-30. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

Amendment to the Claims

Claim 1 is amended to include the limitations of dependent claim 4, which is hereby cancelled. Entry of this amendment after final is respectfully requested since no new matter is added.

Rejections Pursuant to 35 U.S.C. § 103

Shadduck and Ballintyn

Claims 1-2, 6-8, 10-12, and 14-15 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,503,251 ("Shadduck") in view of U.S. Patent No. 5,584,836 ("Ballintyn").

At the outset, Applicants continue to disagree with the Examiner's argument that Shadduck discloses a shank with a distal portion having a minor diameter that decreases in a proximal-to-distal direction and having first and second helical thread extending around the shank to define a thread depth that remains constant along a length of the shank. The Examiner refers to Figure 7 of Shadduck and argues that "at least partial revolutions of the helical threads extend around at least a portion of the proximal and distal portion." *See Office Action, p. 4, lines 4-5.* The Examiner has not pointed to anywhere in the disclosure of Shadduck which teaches this, and Figure 7 certainly does not show the threads extending around a distal portion of the shank having a minor diameter that decreases. In fact, Shadduck teaches that a spiral thread (29) has a substantially constant spiral lead and is defined by a substantially constant insertion periphery having a cylindrical shape. *See Shadduck, Col. 4, lines 41-65.* Regardless, as noted above, claim 1 is amended to include the limitations of claim 4, thereby obviating the basis for this rejection.

Shadduck, Ballintyn, and Schlapfer

Dependent claims 3-5, 9, 13, 18-20, and 23-24 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Shadduck in view of Ballintyn and in further view of Schlapfer. The Examiner

admits that Shadduck and Ballintyn do not disclose the claimed ranges of lengths, specifically that neither reference teaches a distal portion of a shank has a length that comprises at least about 10% of a length of the bone screw, and that has a decreasing minor diameter. As noted above, independent claim 1 is amended to include the limitations of dependent claim 4. With regard to claim 4, since Shadduck's minor diameter only decreases along the distal-most tip, and not along at least about 10% of a length of the bone screw, the Examiner relies on Schlapfer to remedy this deficiency of Shadduck. In particular, the Examiner submits that Schlapfer teaches optimizing the pitch and length of a screw for enhanced biological anchoring and argues that it would have been obvious to one of ordinary skill to have optimized these values with respect to the claimed bone screw. Applicants respectfully disagree.

Schlapfer does not remedy the deficiencies of Shadduck and Ballintyn as Schlapfer does not teach or even suggest a distal portion of a bone screw having a length that is at least about 10% of a length of the bone screw and having a minor diameter that decreases. As shown in Figure 1, Schlapfer discloses a bone screw having three portions: a head (2), a central portion (3), and a front portion (4, i.e., a distal tip). The front portion (4) tapers, however Schlapfer does not discuss the length of this portion, and thus does not teach or even suggest that this portion should have a length that consists of at least about 10% of the length of the bone screw. The central portion does include a tapering segment (32), however this segment is not adjacent to the front portion (4) and thus cannot form part of the claimed "distal portion." Instead, the tapering segment (32) is located between two constant diameter segments (31, 33). Schlapfer therefore fails to teach or even suggest a bone screw having a distal portion with at length that comprises at least about 10% of the length of the bone screw, and that has a decreasing minor diameter.

In fact, Schlapfer does not teach or suggest any length ranges for the various screw segments it discusses. While Schlapfer goes into some numerical detail regarding optimized pitch angles and shank diameters, Schlapfer discloses nothing regarding the lengths of the disclosed screw or its segments. The Examiner points to column 5, lines 43-56 of Schlapfer as disclosing the claimed length, but this section only teaches that the lengths of screw segments can be sized so that there will be optimal gripping of the surrounding bone by the screw. This vague and non-numeric description of screw length certainly does not remedy the deficiencies of Shadduck. No person having ordinary skill in the art, upon reading Schlapfer, would even think to modify the distal tip of Shadduck to

extend along at least about 10% of the length of the bone screw so as to have a decreasing minor diameter along at least about 10% of the length. Such a teaching or suggestion is simply not present in Schlapfer. Again, nothing in Schlapfer suggests any particular length for a shank in numbers, percentages, or otherwise, and it certainly does not suggest a shank having a distal portion with a length that comprises at least about 10% of a length of a bone screw. Schlapfer therefore fails to remedy the deficiencies of Shadduck and Ballintyn.

Furthermore, there is simply no motivation to modify the screw of Shadduck to have a distal portion with a length that comprises at least about 10% of a length of a bone screw and with a decreasing minor diameter. As noted above, Shadduck is specifically directed toward a shank having a substantially constant insertion periphery and a spiral thread (29) having a substantially constant spiral lead. *See Shadduck, Col. 4, lines 41-65.* Modifying the shank to having a decreasing diameter along at least about 10% of a length of the shank at the distal portion would require one to ignore the specific teachings of Shadduck. Accordingly, there would be no motivation to modify Shadduck as suggested by the Examiner.

For all of these reasons, independent claim 1, as well as claims 2, 6-8, 10-12, and 14-15 which depend therefrom, therefore distinguish over Shadduck, Ballintyn, and Schlapfer and represent allowable subject matter.

Claims 16-17, 21-22, and 25-29

Independent claim 16 recites a bone screw having a shank formed from first and second axially symmetrical threads offset approximately 180° from one another and extending around at least a portion of the shank between proximal and distal ends. The threads have a depth that remains constant along a length of the shank, and a proximal portion of the shank has a minor diameter that is equal to or greater than a major diameter of the shank at a distal-most end.

Shadduck fails to teach or even suggest "first and second axially symmetrical threads offset approximately 180 degrees from one another," as required by independent claim 16. In response to Applicant's previous comments, the Examiner argues that "Shadduck discloses that the second axis could be parallel to but laterally offset from the first axis and meets the claim limitation of 'approximately 180 degrees from one another.'" *See Office Action dated August 23, 2007, p. 4, lines*

6-8. This is simply not the case. The section to which the Examiner is referring is describing Figure 7 of Shadduck, which is reproduced herein. By disclosing that the second axis can be parallel to but laterally offset from the first axis, Shadduck is describing the Δ shown in Figure 7 above. This Δ is taught to indicate that the two threads are offset ***sideways*** to one another – ***not positioned 180 degrees from each other*** as required by claim 16. *See Shadduck, Col. 8, lines 29-33.* As further shown in Figure 7 of Shadduck, as well as in the language pointed out by the Examiner, by definition, first and second threads which are laterally offset cannot be ***axially symmetrical***. For all of these reasons, this teaching would not meet the requirements of claim 16.

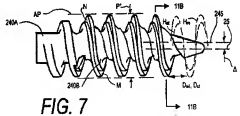

FIG. 7

Ballintyn does not remedy the deficiencies of Shadduck. Ballintyn only discloses one screw thread (2) and thus does not have "first and second axially symmetrical threads offset approximately 180 degrees from one another," as required by claim 16. Accordingly, independent claim 16, as well as claims 17, 21-22, and 25-29 which depend therefrom, distinguish over Shadduck and Ballintyn and represent allowable subject matter.

Claim 30

Independent claim 30 recites a bone screw that includes a head and a shank having a proximal portion with a constant minor diameter, and a distal portion with a minor diameter that decreases in a proximal-to-distal direction. Opposed first and second helical threads are formed on at least the distal portion of the shank and they define a major diameter that decreases at the same rate as the minor diameter of the shank.

At the outset, the Examiner has failed to address why each element of claim 30 is obvious over Shadduck and Ballintyn. Both in the rejection and in the Examiner's response to the Applicants' previous arguments, the Examiner does not address the claim limitation requiring a bone screw having first and second helical threads defining ***a major diameter that decreases at the same rate as a minor diameter of a shank.*** In the Examiner's response to the Applicants' previous arguments, the Examiner states, "Applicants arguments are not directed to claim limitations…the shank of the Shadduck bone screw has a proximal portion with a constant minor diameter and a distal portion with a minor diameter that decreases in a proximal-to-distal direction." *See Office Action*

dated August 23, 2007, p. 4, lines 9-12. As noted above, a reading of claim 30, however, will show that it also requires that opposed first and second helical threads are formed on at least a distal portion of a shank and they define a major diameter that decreases at the same rate as a minor diameter of the shank. As shown in Figure. 1 of Shadduck which is reproduced herein, Shadduck's bone screw has threads with a constant major diameter. The major diameter of the threads does not decrease. Since the diameter of the threads does not decrease, the thread diameter certainly does not decrease at a rate that is the same rate as a minor diameter of the shaft. Thus, claim 30 distinguishes over Shadduck.

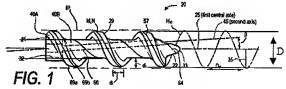

FIG. 1

Ballintyn does not remedy the deficiencies of Shadduck, as Ballintyn likewise fails to teach threads having a major diameter that decreases. Like Shadduck, Ballintyn's screw has threads with a constant major diameter.

Accordingly, independent claim 30 distinguishes over Shadduck and Ballintyn and represents allowable subject matter.

Conclusion

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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